



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,936	01/14/2004	Douglas D. Burkett	65879-5008	6529
24574 7590 07/22/2008 JEFFER, MANGELS, BUTLER & MARMARO, LLP 1900 AVENUE OF THE STARS, 7TH FLOOR LOS ANGELES, CA 90067			EXAMINER WILDER, CYNTHIA B	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 07/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/758,936

Applicant(s)

BURKETT, DOUGLAS D.

Examiner

CYNTHIA B. WILDER

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/2008 has been entered. Claims 1-5 have been canceled. Claims 6-15 have been added. Claims 6-15 are pending and address in this Office action. The previous rejections of the prior Office actions have been withdrawn in view of Applicant's cancellation of the claims.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

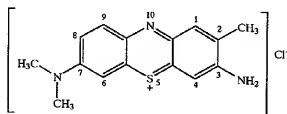
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

Art Unit: 1637

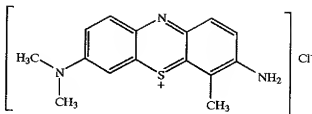
had possession of the claimed invention. The new limitation "wherein said dye comprises:

(1) the conformational isomers of toluidine blue
O, the compounds having the structures

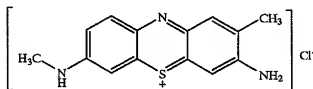


Art Unit: 1637

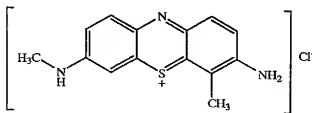
and



(2) the N-demethylation derivatives of said isomers, the compounds having the structures



and



the ratio of the combined areas of the 254 nm HPLC peaks representing said isomers to the combined areas of the peaks representing said N-demethylation derivatives being at least about 6:1;

and the limitation wherein "the steps of manufacturing toluidine blue O, which comprises the steps of (i) oxidizing N,N-dimethyl-p-phenylene diamine in a first reaction mixture, to form a first intermediate, 2- amino-5-dimethylaminophenyl thiosulfonic acid, (2) oxidizing said first intermediate and condensing the oxidizate in a second reaction mixture with o-toluidine, forming a second intermediate, indamine thio- sulfonic acid, (3) oxidizing said second intermediate to close the indamine ring thereof, forming a TBO-containing reaction product dissolved in a third reaction mixture, (4) introducing a complexing reagent into said third reaction mixture, to form a TBO-complex product dissolved in said third reaction mixture, (5) precipitating said TBO-complex product from said third reaction mixture, and (6) separating said TBO-complex product, containing the conformation isomers of TBO; wherein the improved process comprises introducing said complexing reagent to a reaction mixture before the formation of said third reaction mixture, said complexing reagent being a compound that forms with said N,N-dimethyl-p-phenylenediamine said first intermediate and/or said second intermediate, a complex that provides steric hindrance to demethylation thereof" are not supported by the instant invention as originally filed.

Applicant arguments at page 11 states that the specification supports the amendment at pages 6 and 12, which recites that "TBO (e.g., prepared in accordance with Example I of my U.S. Patent No. 6,086,852)..." and "TBO (e.g., the product of Example 1 of U.S. Patent 6,086,852), raspberry flavoring agent (IFF raspberry IC563457), sodium acetate trihydrate buffering agent and H2O2 (30% USP) preservative (see U.S. Patent 5,372,801), are dissolved in purified water (USP), glacial

Art Unit: 1637

acetic acid and SD 18 ethyl alcohol, to produce a TBO test solution, having the composition indicated in Table A.." Applicant submits that the '852 Patent discloses the ratios of the different structures of toluidine blue O (also referred to herein and in the '852 Patent as "peaks"), the percentage(s) by weight of certain structures in the composition, and the methods of preparing the same, as is claimed in the new claims of the present application."

However, it is noted that the information of the Patent 6,086,852 as noted in the example for the preparation of TBO has not been incorporated by reference into the instant specification. Nowhere in the specification is there any teaching of the conformational isomers or N-demethylation derivatives of the isomers or HPLC peaks as currently claimed. No composition structures or HPLC data are presented anywhere in the instant specification. Likewise, the specification provides no steps of manufacturing the TBO dye as currently claimed in the instant specification. The specification at pages 5-6, 10 and 11 teaches:

"[T]BO (e.g., prepared in accordance with Example 1 of my US Patent 6,086,852), raspberry flavoring agent (IFF Raspberry IC563457), sodium acetate trihydrate buffering agent and H2O2 (30% USP) preservative (see U.S. Patent 5,372,801), are dissolved in purified water (USP), glacial acetic acid and SD 18 ethyl alcohol, to produce a TBO test solution, having the composition indicated in Table A: TBO 1.00% by weight, Flavor 0.20% by weight, Buffering agent 2.45% by weight, preservative 0.41% by weight, Acetic acid 4.61% by weight, ethyl alcohol 7.48% by weight and water 83.85% by weight".

MPEP 608.01(p) states that "incorporating by reference material that was not incorporated by reference on filing of an application may introduce new matter". 37

CFR 1.57(b) states that: "[A]n incorporation by reference must be set forth in the

specification and must: (1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"); and (2) Clearly identify the referenced patent, application, or publication." In this case, Applicant does not provide such information by statement that the material is incorporated by reference. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). MPEP further states that "incorporation by reference statement after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a))."

Furthermore, the newly added limitation appears to be essential to the essence of the invention. MPEP 608.01(p) speaks to the issue of the completeness of the specification for the practiced of a claimed invention, stating, "While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention" commensurate fully in scope. In this case, given the lack of information in the instant specification, one skill in the art would not have any knowledge of making the conformational isomers of TBO or manufacture the TBO dye as claimed. Thus, Applicant's specification would not have suggested to the skilled artisan that Applicant was in possession of the claimed invention as of the filing date.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 6-12 are indefinite and lacks proper antecedent basis in the claims 6 and 7 for "the ratio of the combined areas of the 254 nm HPLC peaks" because neither the claims nor specification define or recite any "HPLC peaks" or any "ratio" or any "combined areas" and it cannot be determine what applicant is making reference to. A clear interpretation of Applicant's intent cannot be ascertained.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CYNTHIA WILDER/
Patent Examiner
Art Unit 1637

7/15/2008